4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3926]

Request for Nominations for Voting Members on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. This annual notice is also in accordance with the 21st Century Cures Act, which requires the Secretary of Health and Human Services (the Secretary) to provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], will be given first consideration for membership on the Panels of the MDAC. Nominations received after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal at

https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at https://www.fda.gov/AdvisoryCommittees/default.htm.

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, contact the following persons listed in table 1*:

Table 1.--Primary Contact and Committee or Panel

Primary Contact Person	Committee or Panel
Joannie Adams-White, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5561, Silver Spring, MD 20993, 301-796-5421, Joannie.Adams-White@fda.hhs.gov	Medical Devices Dispute Resolution Panel
James P. Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 Rm. 5211, Silver Spring, MD 20993, 301-796-6313, James.Swink@fda.hhs.gov	Circulatory System Devices Panel, Immunology Devices Panel, Microbiology Devices Panel, Ophthalmic Devices Panel.
Akinola Awojope, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993, 301-636-0512, Akinola.Awojope@fda.hhs.gov	Dental Products Panel, Neurological Devices Panel, Obstetrics and Gynecology Devices Panel Orthopaedic and Rehabilitation Devices Panel.
Jarrod Collier, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993, 301-796-6875, Jarrod.Collier@fda.hhs.gov	Ear, Nose and Throat Devices Panel, General Hospital and Personal Use Devices Panel, Hematology and Pathology Devices Panel, Molecular and Clinical Genetics Panel, Radiological Devices Panel.
Candace Nalls, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993, 301-636-0510, Candace.Nalls@fda.hhs.gov	Anesthesiology and Respiratory Therapy Devices Panel, Clinical Chemistry and Clinical Toxicology Devices Panel, General and Plastic Surgery Devices Panel.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for vacancies listed in table 2:

Table 2.--Expertise Needed, Vacancies, and Approximate Date Needed

Expertise Needed	Vacancies	Approximate Date Needed

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee--Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, sleep medicine, pharmacology, physiology, or the effects and complications of anesthesia. FDA is also seeking applicants with pediatric expertise in these areas.	3	Immediately
Circulatory System Devices Panel of the Medical Devices Advisory Committee--Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1 1	Immediately July 1, 2022
Clinical Chemistry and Clinical Toxicology Panel of the Medical Devices Advisory Committee--Doctors of medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1	March 1, 2022
Dental Products Panel of the Medical Devices Advisory Committee--Dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, oral and maxillofacial surgery, endodontics, periodontology, tissue engineering, snoring/sleep therapy, and dental anatomy.	3	Immediately
Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee--Otologists, neurotologists, and audiologists.	4	Immediately
*General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee--S*urgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	4	Immediately
General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee--Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, human factors experts, or microbiologists/infection control practitioners or experts.	2 1	Immediately January 1, 2022
Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee--Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers, molecular oncology, cancer screening, cancer risk, digital pathology, whole slide imaging; devices utilizing artificial intelligence/machine learning.	3 1	Immediately March 1, 2022
Immunology Devices Panel of the Medical Devices Advisory Committee--Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	7	Immediately

Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee--Experts with cross-cutting scientific, clinical, analytical or mediation skills.	1	October 1, 2022
Microbiology Devices Panel of the Medical Devices Advisory Committee--Infectious disease clinicians (e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric ID specialists, tropical diseases specialists) and clinical microbiologists experienced in emerging infectious diseases; clinical microbiology laboratory directors; molecular biologists with experience in in vitro diagnostic device testing; virologists; hepatologists; or clinical oncologists experienced with tumor resistance and susceptibility.	5 2	Immediately March 1, 2022
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee--Experts in human genetics, molecular diagnostics, and in the clinical management of patients with genetic disorders, and (e.g., pediatricians, obstetricians, neonatologists). Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, bioinformatics, computational genetics/genomics, variant classification, cancer genetics/genomics, molecular oncology, radiation biology, and clinical molecular genetics testing, (e.g., sequencing, whole exome sequencing, whole genome sequencing, non-invasive prenatal testing, cancer screening, circulating cell free/circulating tumor nucleic acid testing, digital PCR, genotyping, array CGH, etc.). Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	2 2	Immediately June 1, 2022
Neurological Devices Panel of the Medical Devices Advisory Committee--Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	2	Immediately
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee--Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	4 1	Immediately February 1, 2022
Ophthalmic Devices Panel of the Medical Devices Advisory Committee--Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision	4	Immediately

scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.		
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee--Orthopaedic surgeons (joint, spine, trauma, reconstruction, sports medicine, hand, foot and ankle, and pediatric orthopaedic surgeons); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, and musculoskeletal engineering; radiologists specializing musculoskeletal imaging and analyses and biostatisticians.	2 2	Immediately September 1, 2022
Radiological Devices Panel of the Medical Devices Advisory Committee--Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging and image analysis.	3 4	Immediately February 1, 2022

I. General Description of the Committee Duties

The MDAC reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in many activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, performs the following duties: (1) advises the Commissioner regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the FD&C Act, (7) advises on the necessity to ban a device, and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies

regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Voting Members

The MDAC with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. A maximum of 122 members shall be standing voting members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Nonvoting Representatives on certain panels of the MDAC. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The current needs for each panel are listed in table 2. Members will be invited to serve

for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see ADDRESSES). Nominations must also specify the advisory panel(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 13, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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